

10/541260

JC14 Rec'd PCT/PTO 30 JUN 2005

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Printed Name	<u>QUEEN THOMAS</u>
Signature	<u>Queen Thomas</u>

**PATENT APPLICATION**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

First Applicant: WATKINS Jeffry Dean, et al.  
Serial No.: PCT/US2004/000290

Group Art Unit:  
Examiner:

PCT Nat'l Entry  
Date: January 8, 2004  
For: TNF-ALPHA BINDING MOLECULES  
Docket No.: X16758M

Conf No.:

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

As a means of complying with the duty of disclosure, Applicants submit an "Information Disclosure Citation In An Application" on a Form PTO-1449 (modified) and provide a copy of each of the listed documents] for consideration by the Examiner.

Since this Statement is being filed in accordance with 37 C.F.R. 1.97(b), Applicants submit that no additional fee is required.

Applicants request consideration of this information.

Respectfully submitted,



MaryAnn Wiskerchen  
Attorney for Applicants  
Registration No. 45,511  
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June 21, 2005

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FORM PTO 1449 (modified)  INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Atty. Docket No. X16758M	Serial No. <b>10/541260</b>
	First Applicant WATKINS Jeffry Dean	
	Application Date January 8, 2003 US Nat'l Entry (if applicable)	Group Art Unit

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pages or Relevant Figures Appear <sup>5</sup>
		Number-Kind Code <sup>2</sup> (if known)			
	AA	US 4,603,106	07/29/1986	Cerami, et al.	
	AB	US 4,677,063	06/30/1987	Mark, et al.	
	AC	US 4,677,064	06/30/1987	Mark, et al.	
	AD	US 4,822,776	04/18/1989	Cerami, et al.	
	AE	US 4,870,163	09/26/1989	Rubin, et al.	
	AF	US 4,879,226	11/07/1989	Wallace, et al.	
	AG	US 5,075,236	12/24/1991	Yone, et al.	
	AH	US 5,118,500	06/02/1992	Hänel, et al.	
	AI	US 5,145,676	09/08/1992	Fahey, III, et al.	
	AJ	US 5,183,657	02/02/1993	Buurman	
	AK	US 5,223,395	06/29/1993	Gero	
	AL	US 5,231,024	07/27/1993	Moeller, et al.	
	AM	US 5,288,852	02/22/1994	Yamada, et al.	
	AN	US 5,360,716	11/01/1994	Ohmoto, et al.	
	AO	US 5,436,154	07/25/1995	Barbanti, et al.	
	AP	US 5,610,279	03/11/1997	Brockhaus, et al.	

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	First Applicant WATKINS Jeffry Dean	
	Application Date January 8, 2003 US Nat'l Entry (if applicable)	Group Art Unit

	AQ	US 5,616,321	04/01/1997	Hector, et al.	
	AR	US 5,616,688	04/01/1997	Cerami, et al.	
	AS	US 5,644,034	07/01/1997	Rathjen, et al.	
	AT	US 5,650,147	07/22/1997	Wolpe, et al.	
	AU	US 5,654,407	08/05/1997	Boyle, et al.	
	AV	US 5,656,272	08/12/1997	Le, et al.	
	AW	US 5,658,570	08/19/1997	Newman, et al.	
	AX	US 5,672,347	09/30/1997	Aggarwal, et al.	
	AY	US 5,686,428	11/11/1997	Eriksson, et al.	
	AZ	US 5,698,195	12/16/1997	Le, et al.	
	AAA	US 5,698,419	12/16/1997	Wolpe, et al.	
	AAB	US 5,700,466	12/23/1997	Wolpe, et al.	
	AAC	US 5,703,206	12/30/1997	Wolpe, et al.	
	AAD	US 5,730,975	03/24/1998	Hotamisligil, et al	
	AAE	US 5,741,484	04/21/1998	Cerami, et al.	
	AAF	US 5,741,488	04/21/1998	Feldman, et al.	
	AAG	US 5,750,105	05/12/1998	Newman, et al.	
	AAH	US 5,760,186	06/02/1998	Cerami, et al.	

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION			First Applicant WATKINS Jeffry Dean			
			Application Date January 8, 2003 US Nat'l Entry (if applicable)		Group Art Unit	
	AAI	US 5,795,967	08/18/1998	Aggarwal, et al.		
	AAJ	US 5,808,029	09/15/1998	Brockhaus, et al.		
	AAK	US 5,817,763	10/06/1998	Cerami, et al.		
	AAL	US 5,849,873	12/15/1998	Cerami, et al.		
	AAM	US 5,859,205	01/12/1999	Adair, et al.		
	AAN	US 5,863,535	01/26/1999	Cerami, et al.		
	AAO	US 5,919,452	07/06/1999	Le, et al.		
	AAP	US 5,942,222	08/24/1999	Wolpe, et al.		
	AAQ	US 5,958,413	09/28/1999	Anagnostopulos, et al.		
	AAR	US 5,959,087	09/28/1999	Rathjen, et al.		
	AAS	US 5,989,836	11/23/1999	Cerami, et al.		
	AAT	US 5,994,510	11/30/1999	Adair, et al.		
	AAU	US 6,015,557	01/18/2000	Tobinick, et al.		
	AAV	US 6,015,558	01/18/2000	Hotamisligil, et al.		
	AAW	US 6,019,969	02/01/2000	Cerami, et al.		
	AAX	US 6,046,309	04/04/2000	Cerami, et al.		
	AAZ	US 6,090,382	07/18/2000	Salfeld, et al.		
	AAZ	US 6,114,517	09/05/2000	Monia, et al.		

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			Application Date January 8, 2003 US Nat'l Entry (if applicable)		Group Art Unit	
	ABA	US 6,177,077 B1	01/23/2001	Tobinick, et al.		
	ABB	US 6,235,281 B1	05/22/2001	Stenzel, et al.		
	ABC	US 6,258,562 B1	07/10/2001	Salfeld, et al.		
	ABD	US 6,270,766 B1	08/07/2001	Feldman, et al.		
	ABE	US 6,277,969 B1	08/21/2001	Le, et al.		
	ABF	US 6,284,471 B1	09/04/2001	Le, et al.		
	ABG	US 6,309,640 B1	10/30/2001	Cerami, et al.		
	ABH	US 6,379,666 B1	04/30/2002	Tobinick		
	ABI	US 6,416,757 B1	07/09/2002	Rathjen, et al.		
	ABJ	US 6,419,927 B1	07/16/2002	Cerami, et al.		
	ABK	US 6,419,934 B1	07/16/2002	Tobinick		
	ABL	US 6,419,944 B2	07/16/2002	Tobinick		
	ABM	US 6,423,321 B2	07/23/2002	Tobinick		
	ABN	US 6,428,787 B1	08/06/2002	Tobinick		
	ABO	US 6,448,380 B2	09/10/2002	Rathjen, et al.		
	ABP	US 6,451,983 B2	09/17/2002	Rathjen, et al.		
	ABQ	US 6,498,237 B2	12/24/2002	Rathjen, et al.		
	ABR	US 6,509,015 B1	01/21/2003	Salfeld, et al.		

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JOHN ASCHENBACH 30 JUN 2005

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INFORMATION DISCLOSURE CITATION IN AN APPLICATION			First Applicant WATKINS Jeffry Dean			
			Application Date January 8, 2003 US Nat'l Entry (if applicable)		Group Art Unit	
	ABS	US 6,537,549 B2	03/25/2003	Tobinick		
	ABT	US 6,555,111 B2	04/29/2003	Wallach, et al.		
	ABU	US 6,593,458 B1	07/15/2003	Rathjen, et al.		
	ABV	US 2003/0204066 A1	10/30/2003	Junming, et al.		
	ABW	US 6,790,444 B2	09/14/2004	Le, et al.		
	ABX	US 6,835,823 B2	12/28/2004	Le, et al.		

# **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	BA	WO 95/03827	02-09-1995	The Kennedy Institute of Rheumatology		
	BB	WO 97/30088	08-21-1997	The Kennedy Institute of Rheumatology		
	BC	WO 98/22137	05-28-1998	The Kennedy Institute of Rheumatology		
	BD	WO 98/51344	11-19-1998	The Kennedy Institute of Rheumatology		
	BE	WO 01/94585 A1	12-13-2001	Celltech R & D Limited		
	BF	WO 02/12502 A2	02-14-2002	Centocor, Inc.		
	BG	WO 03/042247 A2	05-22-2003	Merck Patent GMBH		
	BH	WO 03/083061 A2	10-09-2003	Centocor, Inc.		

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	First Applicant	
	WATKINS Jeffry Dean	
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Application Date	Group Art Unit
	January 8, 2003	
	US Nat'l Entry (if applicable)	

# **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published.	T <sup>6</sup>
	CA	BOYLE, P, et al., "I. A Novel Monoclonal Human IgM Autoantibody which Binds Recombinant Human and Mouse Tumor Necrosis Factor- $\alpha$ ", Cellular Immunology, 1993, pgs. 556-568, Vol. 152	
	CB	BOYLE, P, et al., "II. The B5 Monoclonal Autoantibody Binds to Cell Surface TNF $\alpha$ on Human Lymphoid Cells and Cell Lines and Appears to Recognize a Novel Epitope", Cellular Immunology, 1993, pgs. 569-581, Vol. 152	
	CC	BREEDVELD, FC, et al., "Monoclonal antibody therapy of inflammatory rheumatic diseases", British Medical Bulletin, 1995, pgs. 493-502, Vol. 51, No. 2	
	CD	BRENNAN, FM, et al., "TNF $\alpha$ -A Pivotal Role in Rheumatoid Arthritis?", British Journal of Rheumatology, 1992, pgs. 293-298, Vol. 31	
	CE	BRENSING-KÜPPERS, J, et al., "The human immunoglobulin $\kappa$ locus on yeast artificial chromosomes (YACs)", Gene, 1997, pgs. 173-181, Vol. 191	
	CF	BRINGHMAN, TS, et al., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Application for Affinity Purification, Immunoassays, and as Structural Probes", Hybridoma, 1987, pgs. 489-507, Vol. 6, No. 5	
	CG	COX, JPL, et al., "A directory of human germ-line V $\lambda$ segments reveals a strong bias in their usage", Eur. J. Immunol., 1994, pgs. 827-836, Vol. 24	
	CH	DICK, AD, et al., "Inhibition of tumor necrosis factor activity minimizes target organ damage in experimental autoimmune uveoretinitis despite quantitatively normal activated T cell traffic to the retina", Eur. J. Immunol., 1996, pgs. 1018-1025, Vol. 26	
	CI	ELLIOTT, MJ, et al., "Randomised double-blind comparison of chimeric monoclonal antibody to tumour necrosis factor $\alpha$ (cA2) versus placebo in rheumatoid arthritis", The Lancet, 1994, pgs. 1105-1110, Vol. 344	
	CJ	ELLIOTT, MJ, et al., "Repeated therapy with monoclonal antibody to tumour necrosis factor $\alpha$ (cA2) in patients with rheumatoid arthritis", Lancet, 1994, pgs. 1125-1127, Vol. 344	
	CK	ELLIOTT, MJ, et al., "Treatment of Rheumatoid Arthritis with Chimeric Monoclonal Antibodies to Tumor Necrosis Factor $\alpha$ ", Arthritis and Rheumatism, 1993, pgs. 1681-1690, Vol. 36, No. 12	

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		Application Date January 8, 2003 US Nat'l Entry (if applicable)	Group Art Unit
CL	EXLEY, AR, et al., "Monoclonal antibody to TNF in severe septic shock", Lancet, 1990, pgs. 1275-1277, Vol. 335		
CM	FELDMAN, M, et al., "Anti-Tumor Necrosis Factor- $\alpha$ Therapy of Rheumatoid Arthritis", Advances in Immunology, 1997, pgs. 283-350, Vol. 64		
CN	FENDLY, BM, et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor", Hybridoma, 1987, pgs. 359-369, Vol. 6, No. 4		
CO	FOMSGAARD, A., et al., "Auto-Antibodies to Tumour Necrosis Factor $\alpha$ in Healthy Humans and Patients with Inflammatory Diseases and Gram-Negative Bacterial Infections", Scand. J. Immunol., 1989, pgs. 219-223, Vol. 30		
CP	GRIFFITHS, AD, et al., "Human anti-self antibodies with high specificity from phage display libraries", The EMBO Journal, 1993, pgs. 725-734, Vol. 12, No. 2		
CQ	HAMMERLE, AF, et al., "Serum Proteins and Cytokines for Prediction of Sepsis?", Second Vienna Shock Forum, 1989, pgs. 715-718		
CR	HERVE, P, et al., "Phase I-II Trial of a Monoclonal Anti-Tumor Necrosis Factor $\alpha$ Antibody for the Treatment of Refractory Severe Acute Graft-Versus-Host Disease", Blood, 1992, pgs. 3362-3368, Vol. 79, No. 12		
CS	HINSHAW, LB, et al., "Survival of Primates in LD <sub>100</sub> Septic Shock Following Therapy With Antibody to Tumor Necrosis Factor (TNF $\alpha$ )", Circulatory Shock, 1990, pgs. 279-292, Vol. 30		
CT	JOHNSON, G, et al., "Kabat Database and its applications: 30 years after the first variability plot", Nucleic Acid Research, 2001, pgs. 214-218, Vol. 28, No. 1		
CU	JONES, EY, et al., "Structure of tumor necrosis factor", Nature, 1989, pgs. 225-228, Vol. 338		
CV	JOOP, MH, et al., "The Role of Tumor Necrosis Factor/Cachectin in Septic Shock," Second Vienna Shock Forum, 1989, pgs. 463-466		
CW	KAWASAKI, K, et al., "Evolutionary dynamics of the human immunoglobulin $\kappa$ locus and the germline repertoire of the V $\kappa$ genes", Eur. J. Immunol., 2001, pgs. 1017-1028, Vol. 31		
CX	KAWASAKI, K, et al., "One-Megabase Sequence Analysis of the Human Immunoglobulin $\lambda$ Gene Locus", Genome Research, 1997, pgs. 250-261, Vol. 7		
CY	KEMPENI, J, "Preliminary results of early clinical trials with the fully human anti-TNF $\alpha$ monoclonal antibody D2E7", Ann. Rheum. Dis., 1999, pgs. 170-172, Vol. 58, (Suppl. I)		
CZ	KNIGHT, DM, et al., "Stable expression of cloned human antibody genes in murine myeloma cells", Hum. Antibod. Hybridoma, 1992, pgs. 129-136, Vol. 3		

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CAA	KNIGHT, DM, et al., "Construction and Initial Characterization of a Mouse-Human Chimeric Anti-TNF Antibody", Molecular Immunology, 1993, pgs. 1443-1453, Vol. 30, No. 16.		
CAB	LIANG, C-M, et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin", Biochemical and Biophysical Research Communications, 1986, pgs. 847-854, Vol. 137, No. 2		
CAC	MATHISON, JC, et al., "Participation of Tumor Necrosis Factor in the Mediation of Gram Negative Bacterial Lipopolysaccharide-induced Injury in Rabbits", J. Clin. Invest., 1988, pgs. 1925-1937, Vol. 81		
CAD	MEAGER, A, et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)", Hybridoma, 1987, pgs. 305-311, Vol. 6, No. 3		
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FORM PTO 1449 (modified)		Atty. Docket No. X16758M	Serial No. <b>10/541260</b>
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		First Applicant WATKINS Jeffry Dean	
		Application Date January 8, 2003 US Nat'l Entry (if applicable)	Group Art Unit
	CAM	SILVA, AT, et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- $\alpha$ in Experimental Gram-Negative Shock", JID, 1990, pgs. 421-427, Vol. 162	
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	CAP	TOMLINSON, IM, et al., "The structural repertoire of the human V $\kappa$ domain", EMBO Journal, 1995, pgs. 4628-4638, Vol. 14, No. 18	
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